

The Commonwealth of Massachusetts

Board of Registration in Pharmacy Bureau of Health Professions Licensure 250 Washington Street, Boston, MA 02108-4619

> Tel: 617-973-0960 Fax: 617-973-0980 TTY: 617-973-0988 Pharmacy.Admin@mass.gov

Transfer of Ownership

The following requirements shall apply to any Board of Registration in Pharmacy (Board) licensed or registered facility when a Transfer of Ownership is to occur. An application shall be submitted at least **14 days prior to the transfer of ownership**. Review <u>247 CMR</u> for complete information regarding applicable regulations. If additional information is necessary, please contact the Board office.

<u>Fees</u>: A check or money order for the transfer of ownership application fee and controlled substance registration (if applicable) must be payable to the *Commonwealth of Massachusetts*.

<u>Note</u>: Do not send cash, foreign currency, or electronic funds transfers. There will be a \$23 handling charge for returned checks. **Fees are non-refundable and non-transferable**.

To obtain guidance from the <u>Drug Enforcement Administration (DEA)</u> regarding the impact of a transfer of ownership on the licensure status of an existing DEA Registration, please contact them at the following address:

J.F.K. Federal Building
Drug Enforcement Administration
Room E400
15 New Sudbury Court
Boston, MA 02203-0131
(617) 557-2200

Retain copies of all documents for your records. Do not submit checklist.

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Checklist of Documents to be Submitted

DO NOT SUBMIT CHECKLIST A fully and properly completed and signed and notarized Transfer of Ownership Application (see pages 4-9) and associated fee. \$525 for pharmacies, including nuclear pharmacies \$750 for outsourcing facilities \$900 for wholesale distributors **Resident Facilities Only:** Controlled Substance Registration (CSR) application and associated fee. (see page 8) Non-Resident Facilities Only: If licensed or registered by your home-state, attach a copy of your current home-state license or registration. If not, please provide a statement indicating as to why not. If shipping federally controlled drugs, attach a copy of the facility's current DEA Registration Certificate. If applicable, submit a completed <u>Petition for a Waiver</u> for each regulation and section the facility is requesting to be waived. A list of all state(s) where the facility is licensed or registered. An organizational chart which shows the organization prior to and after the transfer of ownership. Official Bill of Sale: a proposed Bill of Sale maybe submitted with the application, but the final Bill of Sale must be submitted when the sale is complete along with all previously issued permits, licenses, and/or registrations. **Proposed New Ownership:** If the facility is to be owned by an individual(s), provide the name of owner(s), address(es), and Social Security Number(s). If the facility is to be owned by a partnership, provide the partnership name, address, and FEIN number. If the facility is to be owned by a corporation, provide the corporation's name, address, FEIN number, state in which company is incorporated, names of corporate officers and their positions and addresses and either a copy of the: o Articles of Organization, signed, and sealed by the Secretary of State if incorporated in

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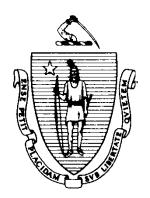
o Foreign Corporation Certificate, signed, and sealed by the Secretary of State pursuant to M.G.L.

Massachusetts: or

c.181, § 4 if incorporated in another state.

Pharmacies (in addition to Documents to be Submitted)
An official blueprint or certified architectural plans drawn to scale (see page 10).
Resident Nuclear Pharmacies Only: A copy of the Radiation Control Program (RCP) license.
Hours of operation (see page 9).
Name, license number, and Social Security number of proposed Manager of Record (MOR).
On a separate sheet of paper briefly describe the <u>business model</u> including any additional services the pharmacy will provide (e.g., compliance packaging, compounding, delivery, immunization, veterinary, long-term care, etc.).
Resident Pharmacies: If proposing to locate within any healthcare facility, documentation of approval from the facility's licensing body(s) must be attached.
Resident Pharmacies: A statement indicating that the Manager of Record will be present if the controlled substances and pharmacy records must be relocated, and that they are aware of their responsibilities in maintaining both security and confidentiality during such transfer.
Documentation attesting that the <u>alarm and all motion detectors/sensors</u> have been tested and are in working order.
Complete the applicable <u>Inspection Template</u> within 30 days. (Do not submit .)
Outsourcing Facilities (in addition to Documents to be Submitted)
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 □ Proof of a <u>valid</u>, <u>current FDA registration</u> pursuant to section 503B of the Federal Food, Drug and Cosmetic Act. □ Proof of <u>FDA Inspection</u> within the last two years. *Proof of inspection may include a copy of the FDA's Notice of Inspection or Form 483, or publication of the inspection date(s) on the FDA website listing 503B registered outsourcing
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 □ Proof of a <u>valid</u>, <u>current FDA registration</u> pursuant to section 503B of the Federal Food, Drug and Cosmetic Act. □ Proof of <u>FDA Inspection</u> within the last two years. *Proof of inspection may include a copy of the FDA's Notice of Inspection or Form 483, or publication of the inspection date(s) on the FDA website listing 503B registered outsourcing facilities. □ Provide a list of the types of <u>entities that you ship to</u> [e.g., patients, hospitals, licensed clinics/surgical centers, practitioners (MD, DMD, DVM, APRM, PA-C), etc.]
 □ Proof of a valid, current FDA registration pursuant to section 503B of the Federal Food, Drug and Cosmetic Act. □ Proof of FDA Inspection within the last two years. *Proof of inspection may include a copy of the FDA's Notice of Inspection or Form 483, or publication of the inspection date(s) on the FDA website listing 503B registered outsourcing facilities. □ Provide a list of the types of entities that you ship to [e.g., patients, hospitals, licensed clinics/surgical centers, practitioners (MD, DMD, DVM, APRM, PA-C), etc.] Wholesale Distributors (in addition to Documents to be Submitted)

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Transfer of Ownership Application

TO BE COMPLETED BY BOARD

C	HECK \$	DATE	
CHECK NO	RECEIPT NO		APP NO
Demographic In	formation		
Legal Name of Facility			
All trade or business name			
License/Registration Num	ber		
FEIN Number:	RCP License No	o. (nuclear pharmacy o	only):
Tel. No	E-n	nail	
NABP e-Profile number (i	f applicable)		
Street Address (physical ac	ddress)		
City/Town	,		
		_ State Zij	
Current Owner(s):			
Name			
Address	City	State	Zip Code
Tal Na	E-1	nail	

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☐ Full-Service Wholesale	r			
Distribution Center for	Pharmacy Corporation			
Other				
Name, phone number, and application:	l email address of the	contact person	for questions regardi	ing this
Name				
Address	City	State	Zip Code	
Tel. No	E-mail _			
Suitability				
Has the applicant or any owner licensed or registered in Massa Yes No If yes, please properties or licenses/registrations/certificate state/jurisdiction from which standing from each state or jurisdiction information.	achusetts? crovide the facility's legal rany owners and corions in the United States the license/registration/cerurisdiction. The verification	name and license of the control of t	r registration number. provide a <u>list of</u> or foreign jurisdiction ginally issued. <u>Include</u>	of any and the proof of
Has the applicant or any owner registered facility that was the revocation of the facility's regiment of the facility's regiment. Yes No If yes, provide	subject of proceedings whi	ich resulted in the o		
Has the applicant or any owner registered facility entered in imposition of discipline on the Yes No If yes, provide	to a settlement agreemen facility's registration or lic	nt in resolution of cense?	•	
	the distribution of drugs (in	cluding samples); by federal, state, all by the applicant	or license for the man	ufacture,

If a Wholesale Distributor, specify type of operation:

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\square Yes \square No If yes, provide a full explanation on a separate page and attach a certified copy of each action and or court setting forth circumstances of such action(s).
Has the applicant or any owner or corporate officer ever been <u>denied licensure</u> by any federal or state agency including any state board of pharmacy? Yes No If yes, provide a full explanation on a separate page.
Is the applicant or any owner or corporate officer the subject of <u>pending disciplinary actions</u> by a licensing/certification board located in the United States or any country or foreign jurisdiction? [Yes No If yes, provide a full explanation on a separate page.
Has the applicant or any owner or corporate officer ever <u>voluntarily surrendered or resigned</u> a professional license to a licensing/certification board in the United States or any country or foreign jurisdiction? [Yes [No If yes, provide a full explanation on a separate page and attach a certified copy of each action and or court setting forth circumstances of such action(s).

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Affidavit (must be signed and notarized)

I certify under the penalties of perjury that I am the person authorized to sign this application and that all information provided is truthful, complete, and for lawful and honest purposes.

I, and my facility, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law pursuant to M.G.L. c. 62C, § 49A.

I have read and understand all applicable state and federal statutes and regulations regarding the operation of the facility and will notify the Board in writing of changes in ownership or management (that do not require an application) within thirty (30) days of such change(s).

Each employed person has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law or regulation.

<u>WARNING:</u> In accordance with M.G.L. c. 94C § 13, the Board of Registration in Pharmacy may suspend or revoke a license or registration to distribute, dispense, or possess a controlled substance after a hearing pursuant to the provisions of Chapter 34A and upon finding that the licensee/registrant has furnished false or fraudulent information in any application filed under the provisions of Chapter 94C.

Name of proposed owner, corporate offic	cer, MOR/PIC Title
Signature	Date
Sworn and subscribed before me this	day of
Notary Public Signature	My commission expires

NOTARY SEAL

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Controlled Substance Registration (CSR) Application

(MA Resident Facilities Only)

I hereby apply for a Controlled Substances Registration in accordance with M.G.L. c. 94C, § 7 with the associated **fee of \$225**. Name of Facility ______License No.____ Street Address
 City/Town
 _____ Zip Code
 Tel. No. ______ E-mail______ FEIN Number: ______ RCP License No. (nuclear pharmacy only): _____ **License / Registration Type:** Outsourcing Facility Wholesale Distributor Pharmacy Please check applicable controlled substance(s): Schedule II Schedule III Schedule IV Schedule V Schedule VI** ** Schedule VI: This substance is any prescription drug that has not already been included in Schedules II-V. Signature of Proposed Owner _____ Printed Name of Proposed Owner TO BE COMPLETED BY BOARD CHECK \$_____DATE____

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CHECK NO. _____RECEIPT NO. _____APP NO. ____

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Hours of Operation

et Address			
/Town		State	Zip Code
No		E-mail	
Days	Open	Closed	Hours
Monday	- 1		
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
~ 1			
Sunday			
Sunday Total hours			
Total hours per week			
Total hours per week or pharmacies, plea eir prescription wh	en the pharmacy is	closed.	pharmacist for question

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Requirements for Certified Blueprints/Architectural Drawings

Drug Store Pharmacy A blueprint/architectural drawing with the pharmacy outlined in RED, drawn to scale with the following items clearly labeled: 1. square footage* 2. prescription area 3. a legend explaining all abbreviations 4. patient consultation area 5. drop off and pickup windows 6. pick-up bins 7. refrigerator 8. safe 9. sink 10. designated non-sterile compounding area (draft 247 CMR 18.00 will require 10 square feet of counter space for non-sterile compounding) 11. other pertinent details * DO NOT include areas such as consultation rooms, front store area, offices, or restrooms in the proposed licensed square footage total. A certified blueprint** with the pharmacy outlined in RED, drawn to scale with **Complex Non-Sterile Compounding Pharmacy** the following items clearly labeled: 1. all requirements listed above for Drug Store Pharmacy 2. designated non-sterile compounding area, if applicable 3. the dedicated compounding room, including placement of containment hood(s) 4. detailed HVAC design plan and written description 5. hazardous drug storage area, if applicable 6. other pertinent details. **Sterile Compounding** A certified blueprint** with the pharmacy outlined in RED, drawn to scale with the following items clearly labeled: **Pharmacy** 1. all requirements listed above for Drug Store Pharmacy 2. designated non-sterile compounding area, if applicable 3. proposed pharmacy layout outlined in red, include square footage of each 4. location and ISO classification of each primary and secondary engineering control 5. air flow 6. room pressurization 7. detailed HVAC design plan and written description 8. location of any pass-throughs 9. hazardous drug storage area, if applicable 10. other pertinent details.

 $\ensuremath{^{**}}$ All blueprints/architectural drawings must be submitted electronically.

A certified blueprint must be stamped with an architect's seal along with the architect's signature.

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